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14 UNITED STATES DISTRICT COURT
15 CENTRAL DISTRICT OF CALIFORNIA

16 POM WONDERFUL LLC, a Delaware
limited liability company,

17 Plaintiff,

18 v.

19 THE COCA COLA COMPANY, a
20 Delaware corporation; and DOES 1-10,
21 inclusive,

22 Defendants.
23

Case No. CV-08-06237 SJO (FMOx)

**PLAINTIFF'S NOTICE OF MOTION
AND MOTION FOR PARTIAL
SUMMARY JUDGMENT RE:
DEFENDANT'S AFFIRMATIVE
DEFENSES OF SAFE HARBOR AND
COMPLIANCE WITH LAWS;
MEMORANDUM OF POINTS AND
AUTHORITIES**

**[Declaration of Daniel A. Beck,
Statement of Uncontroverted Facts and
Conclusions of Law filed concurrently]**

Hon. S. James Otero

Hearing:

Date: January 25, 2010
Time: 10:00 a.m.
Place: Courtroom 1 – 2nd Floor
312 N. Spring Street

PLAINTIFF'S MOTION
FOR PARTIAL SUMMARY JUDGMENT
RE: AFFIRMATIVE DEFENSES

1 TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

2 PLEASE TAKE NOTICE that on January 25, 2010, at 10:00 a.m. or as soon
 3 thereafter as this matter may be heard, in Courtroom 1 – 2nd Floor of the United
 4 States District Court for the Central District of California, 312 North Spring Street,
 5 Los Angeles, California, before the Honorable S. James Otero, United States
 6 District Judge, Plaintiff POM Wonderful LLC (“Pom”) will move and hereby does
 7 move pursuant to Fed. R. Civ. P. 56 for partial summary judgment against defendant
 8 The Coca-Cola Company’s (“TCCC”) Thirtieth Affirmative Defense (Safe Harbor)
 9 and Thirty-Second Affirmative Defense (Compliance with Laws), as alleged by the
 10 Answer which TCCC filed on September 30, 2009 [Docket No. 70].

11 This Motion is based on the grounds that applicable law does not provide a
 12 “safe harbor” or “compliance with laws” affirmative defense to Pom’s claims in this
 13 action, which are asserted pursuant to Lanham Act § 43(a) and Cal. Bus. & Prof.
 14 Code §§ 17200 and 17500.

15 This Motion is supported by this notice of motion and motion, the attached
 16 memorandum of points and authorities, the concurrently filed Declaration of Daniel
 17 A. Beck, the concurrently filed Statement of Uncontroverted Facts and Conclusions
 18 of Law, the [Proposed] Order lodged herewith, such additional evidence and
 19 argument as may be presented at the hearing on this Motion, all of the pleadings,
 20 files and records in this proceeding, and such other evidence as may later be
 21 submitted. The Motion is made following the conference of counsel pursuant to
 22 L.R. 7-3, which took place on December 15, 2009.

23 Dated: December 28, 2009

24 ROLL INTERNATIONAL CORPORATION
 25 LEGAL DEPARTMENT

26 By: /s/ Daniel S. Silverman
 27 Daniel S. Silverman
 28 Attorneys for Plaintiff
 POM WONDERFUL LLC

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1 **MEMORANDUM OF POINTS AND AUTHORITIES**

2 Plaintiff POM Wonderful LLC (“Pom”) moves for partial summary judgment
 3 pursuant to Fed. R. Civ. P. 56 (the “Motion”) against defendant The Coca-Cola
 4 Company’s (“TCCC”) Thirtieth Affirmative Defense (Safe Harbor) and Thirty-
 5 Second Affirmative Defense (Compliance with Laws), as alleged by the Answer
 6 which TCCC filed on September 30, 2009 [Docket No. 70] in response to Pom’s
 7 First Amended Complaint (FAC) [Docket No. 53].

8 **I. INTRODUCTION/SUMMARY OF ARGUMENT**

9 In this action, Pom asserts false advertising claims against TCCC pursuant to
 10 Lanham Act § 43(a), Cal. Bus. & Prof. Code § 17200 (the Unfair Competition Law
 11 or UCL), and Cal. Bus. & Prof. Code § 17500 (the False Advertising Law, or FAL).
 12 Pom’s claims assert that TCCC’s false advertising misleads and deceives consumers
 13 to believe that its Pomegranate Blueberry juice product (the “Juice”) primarily
 14 consists of pomegranate and blueberry juices, when it does not. (FAC, ¶¶ 23-25.)

15 TCCC’s Answer alleges three types of affirmative defenses premised on the
 16 juice product labeling provisions of the Federal Food, Drug, and Cosmetic Act
 17 (FDCA), and various implementing regulations issued by the Food and Drug
 18 Administration (FDA). First, TCCC contends that Pom’s Lanham Act § 43(a) claim
 19 is *precluded*; second, that Pom’s California state law claims are *preempted*; and
 20 third, that TCCC complies with all applicable FDCA provisions and FDA
 21 regulations, thereby providing *safe harbor* against Pom’s false advertising claims.
 22 Pom hereby moves for summary judgment against the last theory, which TCCC’s
 23 Answer alleges in the form of two affirmative defenses:

- 24 ■ The Thirtieth Affirmative Defense (Safe Harbor), alleging that
 25 “Plaintiff’s state law claims are barred by California’s safe harbor
 26 doctrine because TCCC’s alleged actions, at all relevant times and
 27 places, were in compliance with applicable law.”

- 1 ▪ The Thirty-Second Affirmative Defense (Compliance with Laws),
2 alleging that “Plaintiff’s claims are barred because the conduct
3 alleged in the Complaint complies with applicable laws, including
4 but not limited to Food and Drug Administration regulations and
5 the Food, Drug & Cosmetic Act.”

6 The Court should grant summary judgment against these two affirmative
7 defenses because no safe harbor or compliance with laws defense applies to Pom’s
8 false advertising claims. California’s safe harbor doctrine does not apply to a
9 Lanham Act claim, as TCCC’s Answer concedes in explicitly limiting its Thirtieth
10 Defense to Pom’s state law claims. Insofar as TCCC’s Thirty-Second Affirmative
11 Defense attempts to plead the exact same defensive theory against Pom’s Lanham
12 Act § 43(a) claim under the different title “compliance with laws,” it fails for the
13 same reason: A defendant’s compliance with other laws does not immunize it from
14 liability under the Lanham Act. Moreover, as the FAC alleges, Pom’s claims are
15 based on specific deceptive features of the Juice’s label and website that TCCC
16 chose for **marketing** reasons, and which are not required or approved by the FDCA
17 or FDA. For example, the FDA never required TCCC’s marketing-driven decision
18 to call its Juice “Pomegranate Blueberry,” or to display that name in close
19 conjunction with images of a pomegranate and blueberries.

20 To the extent California law permits a safe harbor defense against UCL and
21 FAL claims under certain narrow circumstances, nothing in the FDCA or its
22 implementing regulations establishes such a defense. Pom’s UCL claim alleges that
23 TCCC has violated California’s Sherman Food, Drug and Cosmetic Law, Health &
24 Safety Code § 109875 *et seq.* (the Sherman Law). Section 110660 of the Sherman
25 Law is identical to § 343(a) of the FDCA, stating that “[a]ny food is misbranded if
26 its labeling is false or misleading in any particular.” The FDCA’s imposition of
27 broad statutory liability for false and misleading labeling pursuant to 21 U.S.C. §
28 343(a), and the parallel liability imposed by California’s Sherman Law, are not

1 exhausted by any specific FDCA provisions or FDA implementing regulations. The
2 FDCA's juice labeling provisions and their implementing FDA regulations do not
3 purport to create a "safe harbor" against broader liability (whether imposed under 21
4 U.S.C. § 343(a), other federal law, or state tort law). Indeed, the FDA has never
5 reviewed the label of TCCC's Juice, much less approved it. Moreover, Pom does
6 not contend that any aspect of the Juice's label which is required by the FDCA or
7 FDA regulation is misleading. Accordingly, TCCC's claim that it "complies with
8 laws" has no legal relevance to any claim or defense in this action.

9 Granting this Motion will significantly simplify and streamline the trial.
10 Unlike the preclusion and preemption doctrines (which focus on avoiding legal
11 conflicts), deciding a "safe harbor" or "compliance with laws" defense would hinge
12 upon a close factual analysis of whether TCCC actually complies with specific
13 applicable regulations. Hoping to interject that irrelevant factual dispute into the
14 trial, TCCC has served an expert report by Neal D. Fortin, a food labeling
15 consultant, who in perfunctory and improper fashion makes a legal conclusion that
16 "the statement of identity (name), graphics, and other representations of juice
17 content on the package for the Product comply with all applicable FDA
18 requirements." Mr. Fortin is entirely wrong, as discussed in Pom's forthcoming
19 rebuttal report from Ricardo Carvasal, which will be served on December 31, 2009,
20 pursuant to the parties' stipulated schedule; TCCC's labeling violates multiple
21 provisions of the FDCA and its implementing FDA regulations. But more
22 importantly, whether or not TCCC technically complies with laws does not provide
23 it with an affirmative defense to Pom's claims.

24 Accordingly, the Court should grant summary judgment against TCCC's
25 Thirtieth Affirmative Defense (Safe Harbor) and Thirty-Second Affirmative
26 Defense (Compliance with Laws).¹

27 ¹ Because TCCC's defenses are legally deficient as pled, judgment on the
28 pleadings pursuant to Fed. R. Civ. P. 12(c) would also be appropriate.

II. PROCEDURAL BACKGROUND

TCCC has twice moved to dismiss Pom's claims on the basis of its safe harbor/compliance with laws theory, explicitly with its first motion to dismiss, and implicitly with its second motion to dismiss. On both occasions the Court declined to rule on TCCC's arguments.

A. **The Court Declined To Rule On TCCC's Safe Harbor Defense**

TCCC filed a motion to dismiss [Docket No. 8] against Pom's original complaint. In its February 10, 2009 Order Granting in Part, Denying in Part Defendant's Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(6) [Docket No. 25] (the "MTD Order"), the Court stated that it "declines to determine the issue" of whether the safe harbor doctrine applied to Pom's UCL and FAL claims, citing the Order's rulings on preemption and preclusion. See MTD Order, at p. 14.

B. **The Court Did Not Accept TCCC's Argument That Its Alleged Compliance With The FDCA And Implementing FDA Regulations Preempts Pom's State Law Claims**

On August 10, 2009, TCCC filed a motion to dismiss Pom's FAC [Docket No. 55]. TCCC argued that Pom lacked standing to assert its state law claims, because those claims are preempted by TCCC's alleged compliance with Sections 343(f) and (i) of the FDCA and their corresponding FDA regulations. See Memorandum of Points and Authorities in Support of Motion to Dismiss, at p. 15-18. On September 15, 2009, the Court issued an Order Denying Defendant's Motion to Dismiss First Amended Complaint Pursuant to Fed. R. Civ. P. 12(b)(6) [Docket No. 65], finding that Pom had adequately pled standing to assert its UCL and FAL claims.

III. FACTUAL BACKGROUND

A. **The False And Misleading Label For TCCC's Pomegranate Blueberry Juice Product**

Pom's FAC alleges that the **labeling** of TCCC's Juice is false and misleading in specific respects that are not required by federal or state regulation. The Juice's label is misleading because:

Notwithstanding that Coca Cola's product actually contains little pomegranate or blueberry juice, Coca Cola decided to create a label with many misleading elements not required by federal or state regulation. For example, instead of calling its product "Apple Grape" juice, which are the two primary juices in its product, Coca Cola made a marketing decision to give this product the brand name of "Pomegranate Blueberry" juice on the front label, and to juxtapose this brand name with a picture of a pomegranate and other fruits, among other misleading elements.

(FAC, ¶ 20.) It is undisputed that the Juice's front label displays the following text, from top to bottom:²

Enhanced Juice

Minute

Maid®

100% Fruit Juice Blend

Omega-3/DHA

HELP NOURISH

YOUR BRAIN

² The font for this text is 14 point Times New Roman, as required by Local Rule 11-3.1.1. It is not the same font size that the Juice's front label uses. See Beck Decl., Exh. A.

5 Nutrients to Support Brain & Body

POMEGRANATE

BLUEBERRY

Flavored Blend of 5 Juices

From Concentrate With Added Ingredient

And Other Natural Flavors

See Undisputed Fact (“UF”) No. 1. The Juice’s front label prominently displays a vignette of a large, cut pomegranate and 3 blueberries below the line stating “your brain” and above the line stating “pomegranate.” See UF No. 2. The front label segregates the text “Pomegranate Blueberry Flavored Blend of 5 Juices” from its other text, placing space and illustrations between it. See UF No. 3. In this segregated text group, the words “Pomegranate Blueberry” are displayed in larger font size than the words below, “Flavored Blend of 5 Juices.” See UF No. 4. All of this text is displayed in larger font size than the distinct text group below, which states “From Concentrate With Added Ingredient And Other Natural Flavors.” See UF No. 5.

B. The False And Misleading Webpage For TCCC’s Pomegranate Blueberry Juice Product

Pom’s FAC alleges that the **webpage** for TCCC’s Juice is false and misleading in specific aspects which are not required by federal or state regulation. The Juice’s webpage is misleading because:

In addition to the claims on the product itself, Coca Cola also maintains a website at <minutemaids.com> that prominently advertises and markets Coca Cola’s product as “Minute Maid Enhanced Pomegranate Blueberry” juice.

(FAC, ¶ 21.) TCCC’s webpage for the Juice displays the following text at http://www.minutemaids.com/products/Variety_Juices_and_Drinks/PomegranateBlueberry.jsp:

Minute Maid Enhanced Pomegranate Blueberry is a great tasting flavored 100% juice blend with 50mg of Omega-3/DHA per 8 fl. oz. serving and four other nutrients to help nourish your brain and body.

See UF No. 6. The webpage further states “5 Nutrients in Minute Maid Enhanced Pomegranate Blueberry That Help Support Brain & Body.” See UF No. 7. Thus TCCC’s website is misleading because it identifies the Juice as “Enhanced Pomegranate Blueberry,” without communicating to a reasonable consumer that the product in fact contains very little pomegranate or blueberry juice.

IV. REGULATION OF FALSE AND MISLEADING LABELING

A. The FDCA’s Fundamental Statutory Prohibition Of False And Misleading Labeling – 21 U.S.C. § 343(a)

One of the FDCA’s most fundamental provisions, § 403(a), codified as 21 U.S.C. § 343(a), deems a food misbranded “if its labeling is false or misleading in any particular.” As explained in a treatise written by TCCC’s own designated FDA labeling expert, Neil D. Fortin:

Section 403(a)(1) of the Federal Food Drug & Cosmetic Act ... deems a food misbranded if the labeling is false or misleading in any particular. . . . The courts have upheld a strict standard for misleading labels. Note that statements may be technically accurate but still mislead.

Neal D. Fortin, Food Regulation: Law, Science, Policy, and Practice, at p. 73 (Wiley 2009).³ The Supreme Court elaborated on this point in a leading decision on the “false or misleading” standard which is set forth in the 1906 Food and Drugs Act, and which is incorporated in § 403(a):

³ Available online at: http://books.google.com/books?id=IF7uOv_bD0kC&dq=neil+fortin+food+regulation&source=gbs_navlinks_s.

1 The statute is plain and direct. Its comprehensive terms
 2 condemn every statement, design, and device which may
 3 mislead or deceive. Deception may result from the use of
 4 statements not technically false or which may be literally true.
 5 The aim of the statute is to prevent that resulting from
 6 indirection and ambiguity, as well as from statements which are
 7 false. **It is not difficult to choose statements, designs, and**
 8 **devices which will not deceive.** Those which are ambiguous
 9 and liable to mislead should be read favorably to the
 10 accomplishment of the purpose of the act.

11 U.S. v. Ninety-Five Barrels, 265 U.S. 438, 442-43 (1924) (emphasis added). In
 12 determining whether food labeling is misleading, section 201(n) of the Act requires
 13 that there be taken “into account (among other things) not only representations made
 14 or suggested by statement, word, design, device, or any combination thereof, but
 15 also the extent to which the labeling or advertising fails to reveal facts material in
 16 the light of such representations. . . .” Thus, information that is omitted from a label
 17 may be as important in determining whether the label is misleading as is information
 18 that is disclosed on the label. Also, how the information is conveyed on the label is
 19 important to determining if it is misleading.

20 **B. FDA Regulation Of Juice Labeling: Juice Blends**

21 Pursuant to its statutory authority, the FDA has promulgated regulations
 22 directed at various aspects of labeling for juice blend products. Such regulations
 23 help effectuate the FDCA, but do not purport to replace the general misbranding
 24 liability imposed by 21 U.S.C. § 343(a). To the contrary, the FDA has expressly
 25 recognized that its regulation cannot, and does not, resolve all misleading or
 26 deceptive aspects of the labeling for multiple-juice beverages:
 27
 28

1 FDA agrees that the very nature of these “blends,” mixtures of
 2 several juices, with only one or two minor juices giving them
 3 flavor, makes them difficult to label. The agency, therefore, is
 4 not establishing an exact labeling format for these products.
 5 **However, a common or usual name that misleads**
 6 **consumers to believe that a minor juice, even though it may**
 7 **impart the prominent flavor to the beverage, is present in**
 8 **the greatest amount would be misleading.**

9 Food Labeling; Declaration of Ingredients; Common or Usual Name for
 10 Nonstandardized Foods; Diluted Juice Beverages; Proposed Rule, 56 Fed. Reg.
 11 30462 (July 2, 1991) (emphasis added).

12 As Judge Dean D. Pregerson recently held in the sister case which Pom filed
 13 in the Central District against Ocean Spray Cranberries, Inc.:

14 [D]etermining the primary ingredients of the Beverage and
 15 whether Defendant’s representations are misleading is not
 16 contingent on a decision of fact by the FDA or the enforcement
 17 of its regulations. [] To the contrary, the regulations notably
 18 do not define what constitutes a label that is “false or
 19 misleading.” See 21 U.S.C. § 343(a).

20 Pom Wonderful LLC v. Ocean Spray Cranberries, Inc., 642 F. Supp. 2d 1112, 1119
 21 (C.D. Cal. 2009) (hereinafter Ocean Spray) (citations omitted).

22 In summary, manufacturers bear the ultimate responsibility to name and label
 23 their products in a manner that is neither false nor misleading under 21 U.S.C. §
 24 343(a) (*i.e.* Section 403(a) of the FDCA), and that overarching responsibility is not
 25 excused or satisfied by technically complying with specific FDA juice labeling
 26 regulations.

**V. APPLICABLE LAW DOES NOT PROVIDE A “SAFE HARBOR” OR
“COMPLIANCE WITH LAWS” DEFENSE TO POM’S CLAIMS**

A. Legal Standard For Summary Judgment

Summary judgment is appropriate when the moving party demonstrates that “there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c). As the Supreme Court has explained, “[t]he mere existence of a scintilla of evidence in support of the [claimant’s] position will be insufficient” to overcome summary judgment. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252 (1986).

B. As A Matter Of Law, “Safe Harbor” And “Compliance With Laws” Are Not Affirmative Defenses To Pom’s Lanham Act § 43(a) Claim

TCCC’s Answer pleads a “Compliance with Laws” defense against all three of Pom’s claims, but only pleads its “Safe Harbor” defense against Pom’s state law claims pursuant to the UCL and FAL, conceding that California’s safe harbor doctrine does not apply to Pom’s Lanham Act § 43(a) claim. TCCC’s retitling of its safe harbor defense as “compliance with laws,” however, does not render the same defensive theory applicable to the Lanham Act. Both defenses assert that TCCC’s purported compliance with a specific statute or regulation provides immunity to broader types of legal liability. But no federal court appears to have recognized that such a defense applies to a Lanham Act § 43(a) false advertising claim, whether the defense is entitled safe harbor, compliance with law, or any other name. Thus partial summary judgment should be granted against TCCC’s attempt to assert a “compliance with laws” affirmative defense against Pom’s Lanham Act § 43(a) claim.

Moreover, as explained below in the context of Pom’s UCL and FAL claims, a safe harbor/compliance with laws defense cannot be asserted here because the FDA has not reviewed and approved the specific advertising statements in dispute

1 here, nor propounded regulations that create a safe harbor for claims directed at such
2 statements. No law or regulation required TCCC to make these statements.

3 Instead of recognizing a “compliance with laws” defense, federal courts have
4 typically analyzed the relationship between federal regulation and the Lanham Act
5 in the context of the preclusion doctrine. And under that doctrine, “so long as courts
6 are not required to perform ‘authoritative interpretation and direct application of
7 FDA regulations,’ then the simple fact that a matter touches upon an area dealt with
8 by the FDA is not a bar to proceeding with a claim under the Lanham Act.” Mutual
9 Pharm. Co. v. Ivax Pharms., Inc., 459 F. Supp. 2d 925, 935 (C.D. Cal. 2006)
10 (quoting Summit Technology v. High-Line Medical Instruments Co., 933 F. Supp.
11 918, 933 (C.D. Cal. 1996)). Accordingly, TCCC’s purported compliance with laws
12 does not constitute an affirmative defense to Pom’s Lanham Act claim.

13 **C. As A Matter Of Law, “Safe Harbor” And “Compliance With Laws” Do**
14 **Not Provide TCCC With Affirmative Defenses To Pom’s UCL And FAL**
15 **Claims**

16 California law permits a safe harbor defense under certain specific
17 circumstances, but those circumstances are not present here. None of the
18 regulations relied on by TCCC purport to create a safe harbor or – as TCCC
19 alternatively terms its theory – a “compliance with laws” defense. The FDA has
20 never reviewed the Juice’s label and determined that it does not mislead consumers
21 regarding the product’s juice contents. Pom’s claims are based on specific false and
22 misleading aspects of the label that are *not* required by the FDCA or its
23 implementing FDA regulations. As a matter of law, TCCC thus cannot show that
24 California’s safe harbor doctrine (or an equivalent doctrine entitled “compliance
25 with laws”) applies to bar Pom’s UCL and FAL claims.

26 **1. Legal Standard For California’s Safe Harbor Doctrine**

27 This Court’s MTD Order [Docket No. 25] succinctly summarized California’s
28 safe harbor doctrine as follows:

1 The safe harbor doctrine “simply holds that a plaintiff may not
 2 bring an action under [California Business and Professions
 3 Code § 17200 that] challeng[es] business practices specifically
 4 permitted by other statutes.” McKell, et al. v. Wash. Mut., Inc.,
 5 et al., 142 Cal. App. 4th 1457, 1474 (Cal. Ct. App. Sept. 18,
 6 2006). Specifically, the safe harbor doctrine provides that “[i]f
 7 the Legislature has permitted certain conduct or considered a
 8 situation and concluded no action should lie, courts may not
 9 override that determination.” Cel-Tech Commc’ns, Inc., et al.
 10 v. Los Angeles Cellular Tel. Co., 973 P.2d 527, 541 (1999).
 11 For the safe harbor doctrine to apply, the legislation must
 12 “actually ‘bar’ the action or clearly permit the conduct.” Id. In
 13 other words, “courts may not use the unfair competition law to
 14 condemn actions the Legislature permits. Conversely, the
 15 Legislature’s mere failure to prohibit an activity does not
 16 prevent a court from finding it unfair.” Id. at 542.

17 Id., at pp. 13-14.

18 **2. The FDCA’s Juice Labeling Provisions And The FDA’s**
 19 **Implementing Regulations Do Not “Actually Bar” Pom’s UCL And**
 20 **FAL Claims**

21 A statute or regulation may *expressly* create a specific liability exemption (*i.e.*
 22 safe harbor) which bars liability for certain conduct. But the FDCA’s juice labeling
 23 provisions do not purport to bar or limit false advertising liability more broadly,
 24 whether imposed pursuant to 21 U.S.C. § 343(a), other federal law, or state tort law.
 25 Neither do the implementing FDA regulations. TCCC erroneously implies that its
 26 general legal obligations not to mislead consumers with its labeling, as imposed by
 27 21 U.S.C. § 343(a) and non-conflicting state tort laws, are satisfied if its labeling
 28 complies with specific FDA regulations. The fundamental defect in TCCC’s

1 position is that Congress, the FDA, the FDCA, and FDA regulations do not indicate
 2 that such regulations establish a safe harbor which “actually bars” Pom’s claims. In
 3 fact, they indicate the opposite.

4 In stark contrast to TCCC’s attempted invocation of an *implied* safe harbor
 5 with uncertain scope, Congress has consistently utilized *express* safe harbor
 6 provisions with certain scope when it has intended to provide a safe harbor, or
 7 otherwise restrict broader liability claims. A typical example is provided by the
 8 Food and Drug Administration Modernization Act of 1997 (FDAMA). Part of the
 9 FDAMA, the former 21 U.S.C. § 360aaa-6(b), provided that as long as a
 10 manufacturer complied with certain limitations, its dissemination of information
 11 about off-label uses of a medical device would “not be construed by the Secretary as
 12 evidence of a new intended use of the drug or device that is different from the
 13 intended use of the drug or device set forth in the official labeling of the drug or
 14 device.” Accordingly, “[u]nder this safe harbor, then, the manufacturer could
 15 disseminate information about an off-label use of a device without triggering the
 16 duty to provide instructions or warnings about that off-label use.” Riley v. Cordis
 17 Corp., 625 F. Supp. 2d 769, 782 (D. Minn. 2009). As Congress and the FDA
 18 manifestly know how to draft safe harbor provisions when they intend to, “[t]he
 19 statute made clear that this safe harbor applied “[n]otwithstanding subsection (a),
 20 (f), or (o) of section 352 of this of this title, or any other provision of law....” Id.
 21 (quoting 21 U.S.C. § 360aaa-6(b)).

22 Similarly, another express safe harbor provision is found in 21 U.S.C. §
 23 343(r)(5)(D), part of the FDCA, which “created a similar safe harbor for health
 24 claims on dietary supplements, but delegated to the FDA the task of establishing a
 25 ‘procedure and standard respecting the validity of [the health] claim.’ ” Pearson v.
 26 Shalala, 164 F.3d 650, 653 (D.C. Cir. 1999). Congress thus created an express safe
 27 harbor exempting such supplements from onerous drug regulations, while leaving
 28 them subject to the FDA’s broader regulatory authority for misleading statements.

1 In contrast, TCCC cannot identify any similar statutory or regulatory safe
 2 harbor provision that supports its position. The reason is because the FDA has
 3 unequivocally taken the opposite position:

4 The agency, therefore, is not establishing an exact labeling
 5 format for [juice blend] products. **However, a common or**
 6 **usual name that misleads consumers to believe that a minor**
 7 **juice, even though it may impart the prominent flavor to the**
 8 **beverage, is present in the greatest amount would be**
 9 **misleading.**

10 Food Labeling; Declaration of Ingredients; Common or Usual Name for
 11 Nonstandardized Foods; Diluted Juice Beverages; Proposed Rule, 56 Fed. Reg.
 12 30462 (July 2, 1991) (emphasis added); see also Neal D. Fortin, Food Regulation:
 13 Law, Science, Policy, and Practice, at p. 73 (Wiley 2009) (Section 403(a)(1)
 14 imposes a strict standard, such that a labeling statement “may be technically
 15 accurate but still mislead.”). In maintaining that its label’s purported compliance
 16 with FDA juice labeling regulations means it cannot mislead consumers, TCCC
 17 contradicts the FDA’s stated position, the statutory language, its own expert’s recent
 18 published opinion, and basic common sense.

19 This absence of an express safe harbor provision is particularly important
 20 because, as the Court has previously noted, “the presence of an express preemption
 21 provision, like that in the FFDCA, ‘implies—i.e., supports a reasonable inference—
 22 that Congress did not intend to pre[]empt other matters’ beyond the reach of this
 23 provision.” MTD Order, At 11 (quoting Freightliner Corp., et al. v. Myrick, et al.,
 24 514 U.S. 208, 288 (1995)). When enacting the FDCA, Congress created an express
 25 *preemption* provision, § 343-1, but did not create an express safe harbor against the
 26 misbranding liability imposed by Section 343(a) or equivalent state law.⁴ As Judge

27 ⁴ Pom’s UCL claim is based on a provision of the Sherman Law which is
 28 identical to the FDCA, and therefore not pre-empted by Section 343-1. See Farm

1 Pregerson held in Ocean Spray, “[a]gain, there is no preemption language under §
 2 343-1 which addresses a false or misleading label or, for that matter, the breadth of
 3 issues indicated by an unfair competition law.” Ocean Spray, 642 F. Supp. 2d at
 4 1122. Judge Pregerson thus rejected field preemption because:

5 Congress therefore “made clear that the preemptive scope of
 6 [the FDCA’s express preemption provision] was to sweep no
 7 further than the plain language of the statute itself.” Although
 8 there are indeed a number of food-labeling requirements
 9 promulgated by the FDA, as described in detail above, the
 10 Court thus finds that Congress did not intend federal law to
 11 exclusively occupy the fields of food labeling and advertising.

12 Id. at 1123 (quoting In re Farm Raised Salmon Cases, 42 Cal. 4th 1077, 1091
 13 (2008)). If Congress or the FDA had intended to bar broader liability based on
 14 compliance with laws or regulations, they would have done so by express statutory
 15 or regulatory language. They did not. Just as the Court denied TCCC’s argument
 16 for implied preemption (see MTD Order at 11-13), it should deny TCCC’s even
 17 weaker argument for an implied safe harbor, as FDCA provisions and FDA
 18 regulations do not “actually bar” Pom’s claims. See Cel-Tech, 20 Cal. 4th at 183.

19 **3. Pom’s UCL And FAL Claims Do Not Challenge Conduct Which**
 20 **The FDCA’s Juice Labeling Provisions Or Their Implementing**
 21 **FDA Regulations “Clearly Permits”**

22 Not only do the FDCA’s labeling provisions and their implementing FDA
 23 regulations not “actually bar” Pom’s false advertising claims, such regulations also
 24 do not “clearly permit the conduct” which Pom claims is false and misleading, the
 25 only other basis for presenting a safe harbor defense under California law. See Cel-

26 Raised Salmon, 42 Cal. 4th at 1093 (“[P]laintiffs do not seek to enforce the FDCA.
 27 Their action is based on the violation of *state law*-albeit state law that is, in
 28 compliance with section 343-1, identical to FDCA provisions.”) (emphasis in
 original).

1 Tech, 20 Cal. 4th at 183 (safe harbor doctrine requires that claims are actually
 2 barred or conduct is clearly permitted). Pom claims that TCCC's labeling is false
 3 and misleading because it chose to use the name "Pomegranate Blueberry" for its
 4 Juice, and display those terms prominently in conjunction with a visual depiction of
 5 a pomegranate and blueberries, violating its obligations under the Sherman Law
 6 (and its FDCA parallel in 21 U.S.C. § 343(a)). No FDCA provision or FDA
 7 regulation "clearly permits" TCCC to select that particular name and imagery. Still
 8 less can TCCC maintain that the FDA has reviewed and approved its Juice's label.
 9 The FDA has never issued any such approval.

10 As Judge Pregerson held in the sister case of Ocean Spray, Pom's false
 11 advertising claims are not directed at conduct which is contingent upon FDA
 12 determinations regarding labeling:

13 The "readily verifiable" allegation or fact of Defendant's
 14 marketing representations does not directly or indirectly usurp
 15 the FDA's role, because determining the primary ingredients of
 16 the Beverage and whether Defendant's representations are
 17 misleading is not contingent on a decision of fact by the FDA
 18 or the enforcement of its regulations. [] To the contrary, the
 19 regulations notably do not define what constitutes a label that is
 20 "false or misleading." See 21 U.S.C. § 343(a) ("A food shall be
 21 deemed to be misbranded ... [i]f [] its labeling is false or
 22 misleading in any particular")

23 Ocean Spray, 642 F. Supp. 2d at 1119 (citations omitted). Judge A. Howard Matz
 24 ruled similarly in another sister case which Pom filed against Welch Food, Inc.:
 25 "Put another way, Pom could establish that Welch's labeling is misleading even if
 26 the FDA regulations set mandatory standards for when a beverage may include an
 27 image of a fruit on the label." Pom Wonderful LLC v. Welch Foods, Inc., No. CV
 28 09-567 AHM at p.7 (C.D. Cal. June 23, 2009) (minute order) (attached as Exhibit C

1 to the Declaration of Daniel A. Beck). The bottom line is that Pom's claims are not
2 contingent upon such FDA regulations, which do not "clearly permit" the
3 misleading advertising content that Pom's claims are directed at.

4 Nonetheless, TCCC has erroneously maintained that FDA regulations permit
5 it to use any juice in the product's name so long as its label says that the product is
6 "flavored" with such juice. But no FDA regulation "clearly permits" all such
7 names, finding that they do not mislead consumers (and therefore immunizing a
8 manufacturer from liability under broader law, such as 21 U.S.C. § 343(a)). Instead,
9 the FDA has stated that "a common or usual name that misleads consumers to
10 believe that a minor juice, even though it may impart the prominent flavor to the
11 beverage, is present in the greatest amount **would be misleading.**" Food Labeling;
12 Declaration of Ingredients; Common or Usual Name for Nonstandardized Foods;
13 Diluted Juice Beverages; Proposed Rule, 56 Fed. Reg. 30462 (July 2, 1991)
14 (emphasis added); see also Neal D. Fortin, Food Regulation: Law, Science, Policy,
15 and Practice, at p. 73 (Wiley 2009) (Section 403(a)(1) imposes a strict standard,
16 such that a labeling statement "may be technically accurate but still mislead."). As
17 such, even if pomegranate and blueberry juices imparted a characterizing flavoring
18 to TCCC's Juice – which they do not, because the Juice actually only contains them
19 in miniscule token quantities – FDA regulations do not "clearly permit" TCCC to
20 use the terms "pomegranate" and "blueberry" to form the name it chose for
21 marketing reasons, "Pomegranate Blueberry." Thus the safe harbor doctrine is
22 inapplicable as a matter of law.

1 **VI. CONCLUSION**

2 For the reasons set forth above, the Court should issue an order granting
3 partial summary judgment against the Thirtieth Affirmative Defense (Safe Harbor)
4 and Thirty-Second Affirmative Defense (Compliance with Laws) set forth in
5 TCCC's Answer to the First Amended Complaint.

6 Dated: December 28, 2009

ROLL INTERNATIONAL CORPORATION
LEGAL DEPARTMENT

8
9 By: /s/ Daniel S. Silverman

Daniel S. Silverman
Attorneys for Plaintiff
POM WONDERFUL LLC

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